K131125

6. Summary of Safety and Effectiveness

"510(K) SUMMARY"

JUL 5 2013

Submitted By/
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Date Prepared: April 19, 2013

7.1 Trade/Proprietary Name: Clickfine Pen Needle

7.2 Common/Usual Name: Injection Pen Needle

7.3 Classification Name: Hypodermic single lumen needle

7.4 Classification: FDA has classified Hypodermic single lumen needles in Class II. Final Order was published in the Federal Register on October 21, 1980 after review by the General Hospital and Personal Use Devices Classification Panel.

Panel: 80 Procode: FMI

7.5 Purpose of Submission: To make an administrative change to revise the Indications for Use to be consistent with the BD Injection Pen Needles so that the needles can be marketed Over the Counter (OTC) for all compatible injection pens.

7.6 Substantial Equivalence: The Clickfine Pen Needle is substantially equivalent to the Clickfine Pen Needles (K122969 and K122971) and the BD Pen Needles (K110105, K100005 and K051899).

7.7 Device Description
The Clickfine Pen Needles are sterile, non-pyrogenic, single use needles designed to be used with commercially available pen-injectors for the administration of prescribed fluids. Each needle is individually packaged in a sealed protective container with a peel tab. The pen needles are used by peeling back the peel tab and snapping or screwing the hub onto the threaded end of the pen injector. The back end of the cannula punctures the rubber injection port of the drug reservoir in the pen-injector. The outer protective cap is then removed. The inner protective cap will remain over

the needle until the insulin is ready to be injected. When the injection is needed, the inner protective cap is removed and the needle is inserted into the chosen site. The pen-injector automatically delivers the fluid through the needle. The protective cap is replaced and the needle is then removed, safely discarded and replaced with a new needle.

7.8 Intended Use

The intended use of the device has been modified to combine the Indications cleared for the Clickfine Pen Needle (K122969 and K122971) with the wording in the predicate device BD Pen Needle (K110105, K100005 and K051899):

The Clickfine Pen Needle is intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.

7.9 Technological Characteristics

The technological characteristics have not changed.

7.10 Performance and Safety Data

As this was an administrative change, no performance and safety data were required to be submitted in support of the change.

7.11 Conclusion

Ypsomed AG concludes based on the information presented that the product is substantially equivalent to the current products legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 5, 2013

Ypsomed AG
Dr. Benjamin Reinmann
Vice President
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SWITZERLAND CH-3401

Re: K131125
Trade/Device Name: Clickfine Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 19, 2013
Received: April 22, 2013

Dear Dr. Reinmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131125

Device Name: Clickfine Pen Needle

Indications For Use: The Clickfine Pen Needle is intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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